

Claims

- 5 1. A delivery system for delivery and deployment of a self expanding stent to a desired vascular location of a patient, the system comprising;
- a catheter shaft having a proximal end and a distal end, the distal end of the shaft defining a reception space for receiving a self expanding stent, the stent having a reduced diameter delivery configuration;
- 10 an inner core engagable with the proximal end of the stent;
- an operator handle for movement of the catheter shaft relative to the inner core to deploy the self expanding stent;
- 15 a stabiliser component;
- the inner core being fixed to the stabiliser component, at least during deployment of the self expanding stent.
- 20 2. A delivery system as claimed in claim 1 wherein the inner core has an abutment which is engagable with the proximal end of the stent to deploy the stent.
- 25 3. A delivery system as claimed in claim 2 wherein the inner core has a reduced diameter distal portion extending distally of the abutment at least partially through the stent in the reduced diameter delivery configuration of the stent.
- 30 4. A delivery system as claimed in claim 3 wherein the inner core forms a tubular member in the region of abutment.

5. A delivery system as claimed in claim 4 wherein the inner core has high compressive stiffness.
6. A delivery system as claimed in claim 5 wherein the inner core is of a composite, or a metallic construction.
7. A delivery system as claimed in claim 1 wherein the catheter shaft comprises a distal sheath and a stent is frictionally coupled to the distal sheath in the delivery configuration.
8. A delivery system as claimed in claim 7 wherein the inner core has an abutment which is engagable with the proximal end of the stent to decouple the stent and distal sheath to deploy the stent.
9. A delivery system as claimed in any of claims 1 to 8 wherein the catheter shaft comprises a distal sheath portion and a proximal shaft portion, the diameter of the proximal shaft portion being smaller than the diameter of the distal sheath portion.
10. A delivery system as claimed in claim 9 wherein the stabiliser component is disposed over the smaller diameter proximal shaft.
11. A delivery system as claimed in claim 10 wherein the stabiliser comprises a tube and the diameter of the stabiliser tube is not greater than the diameter of the distal sheath of the catheter shaft.
12. A delivery system as claimed in any of claims 9 to 11 wherein the catheter shaft has a guidewire exit port which is located proximally of the distal end of the catheter shaft.

13. A delivery system as claimed in claim 12 wherein the guidewire exit port is located proximally of the stent.
- 5 14. A delivery system as claimed in claim 12 or 13 wherein the guidewire exit port is located proximally of the delivery sheath.
- 10 15. A delivery system as claimed in any of claims 12 to 14 wherein the guidewire exit port is located at a transition between the distal sheath and the reduced diameter proximal shaft portion.
16. A delivery system as claimed in any of claims 12 to 15 wherein the guidewire exit port is located distally of the stabiliser component.
- 15 17. A delivery system as claimed in any of claims 12 to 16 wherein the guidewire exit port is configured to exit along an axis that is substantially parallel to a longitudinal axis of the distal sheath.
- 20 18. A delivery system as claimed in claim 1 wherein the system comprises a guidewire and the sum of the diameter of the guidewire and the diameter of the proximal shaft is less than the diameter of the distal sheath.
- 25 19. A delivery system as claimed in claim 1 wherein the sum of the diameter of the guidewire and the diameter of the stabiliser component is less than the diameter of the distal sheath.
20. A delivery system as claimed in claim 1 wherein the inner core comprises a large diameter distal segment , a reduced diameter proximal segment , and a transition segment between the distal and proximal segments.

21. A delivery system as claimed in claim 20 wherein the transition segment is proximal of the abutment region.
22. A delivery system as claimed in claim 20 wherein the transition segment is distal of the exit port.
23. A delivery system as claimed in claim 1 wherein the stent directly engages the distal sheath and is slidable relative to the sheath.
24. A delivery system as claimed in claim 23 wherein the distal sheath is a composite with a low friction inner surface
25. A delivery system as claimed in claim 24 wherein the distal sheath is reinforced to withstand the radial stresses of the stent in its constrained reduced diameter configuration.
26. A system as claimed in any of claims 1 to 25 wherein the inner core is fixed to a component of the delivery system.
27. A system as claimed in any of claims 1 to 26 wherein the component of the system to which the inner core is fixed comprises the handle.
28. A system as claimed in any of claims 1 to 27 wherein the stabiliser component is fixed to a procedural catheter.
29. A system as claimed in claim 28 wherein a haemostasis gasket is provided between the stabiliser component and the procedural catheter.
30. A system as claimed in claim 28 wherein the catheter is an introducer sheath.

31. A system as claimed in claim 30 wherein the introducer sheath has an integral haemostasis gasket.
- 5 32. A system as claimed in claim 28 wherein the procedural catheter is a guide catheter.
33. A system as claimed in claim 32 wherein the guide catheter has a haemostasis gasket attachment.
- 10 34. A system as claimed in claim 33 wherein the gasket is adjustable by the operator.
35. A system as claimed in claim 34 wherein the gasket attachment is a Touhy Borst.
- 15 36. A system as claimed in any of claims 1 to 35 wherein the system comprises a procedural guidewire and the guidewire is fixed or fixable to the stabiliser component.
- 20 37. A system as claimed in any of claims 1 to 36 wherein the stabiliser component is length adjustable.
38. A system as claimed in any of claims 1 to 37 wherein the stabiliser component comprises at least two parts which are movable relative to one another.
- 25 39. A system as claimed in claim 1 wherein the stabiliser component position is adjustable.
40. A system as claimed in claim 39 wherein the stabiliser component is adjusted by rotation of a threaded element which provides a position control device.
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41. A system as claimed in any of claims 1 to 40 wherein an intermediate component is provided between the stabiliser component and the inner core.
- 5 42. A system as claimed in claim 41 wherein the intermediate component comprises the handle.
43. A system as claimed in claim 41 wherein the intermediate component comprises at least one bridging piece.
- 10 44. A system as claimed in claim 43 wherein the bridging piece extends through the wall of the proximal shaft.
45. A system as claimed in claim 44 wherein the bridging piece projects laterally of the inner core and/or the stabiliser component.
- 15 46. A system as claimed in claim 45 wherein the bridging piece projects radially between the inner core and the stabiliser component.
- 20 47. A system as claimed in claim 1 wherein the stabiliser component and the inner core are directly mounted to one another.
48. A system as claimed in claim 47 wherein the stabiliser component is melded to the inner core.
- 25 49. A system as claimed in claim 48 wherein the stabiliser component is melded by a welding, gluing, joining, laminating, or bonding process.
- 30 50. A system as claimed in claim 47 to 49 wherein the stabiliser component and the inner core are directly mounted to one another proximal of the distal outer sheath .

51. A system as claimed in claim 50 wherein the stabiliser component and the inner core are directly mounted to one another proximal of the outer shaft.
52. A system as claimed in claim 1 wherein the system includes a guidewire and the guidewire extends at least the length of the catheter shaft.
53. A system as claimed in claim 52 wherein the inner core defines a guidewire lumen along the length thereof.
54. A system as claimed in claim 52 or 53 wherein the system includes a lock for the guidewire.
55. A system as claimed in claim 54 wherein the lock is located proximal of the handle.
56. A system as claimed in claim 1 wherein the stabiliser component comprises a tubular element and the tubular element has a tapered distal end.
57. A system as claimed in claim 1 wherein the system includes a guidewire and the guidewire is located within the profile of the stabiliser component
58. A system as claimed in claim 1 wherein the stabiliser component has a proximal opening to allow backflow of blood.
59. A system as claimed in claim 1 wherein the stabiliser component extends substantially the length of the catheter shaft.
60. A delivery system for delivery and deployment of a self expanding stent to a desired vascular location of a patient, the system comprising:

a catheter shaft having a proximal end and a distal end, the distal end of the shaft defining a reception space for receiving a self expanding stent, the stent having a reduced diameter delivery configuration;

5 an inner core engagable with the proximal end of the stent;

an external mounting for the inner core; and

an operator actuating element for the catheter shaft;

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the operator actuating element being movable proximally of the external mounting for movement of the catheter shaft relative to the inner core to deploy the self expanding stent.

15 61 A delivery system as claimed in claim 60 wherein the operator handle is a pull handle for pulling the catheter shaft proximally relative to the inner core to deploy the self expanding stent.

20 62 A delivery system as claimed in claim 60 or 61 wherein the catheter shaft and the operating handle or interconnected by a connector.

63 A delivery system as claimed in claim 62 wherein the connector extends proximally of the external mounting.

25 64 A delivery system as claimed in claim 63 wherein the connector extends through the external mounting.

65 A delivery system as claimed in any of claims 62 to 64 wherein the connector comprises an elongate member.

66 A delivery system as claimed in claim 65 wherein the elongate member comprises a pull wire.

67 A delivery system as claimed in any of claims 60 to 66 wherein the inner core
5 is fixed internal of the external mounting.

68 A delivery system as claimed in any of claims 60 to 66 wherein a guidewire exit port is provided at the proximal end of the external mounting.

10 69 A method for delivery and deployment of a self expanding stent comprising the steps of:

providing a delivery system comprising a catheter shaft having a proximal end and a distal end, the distal end of the shaft defining an
15 outer sheath having a reception space for receiving a self expanding stent, the stent having a reduced diameter delivery configuration;

an inner core engaging the proximal end of the stent;

20 an operator handle for movement of the catheter shaft relative to the inner core to deploy the self expanding stent;

introducing the delivery system into a vasculature of a patient;

25 delivering the stent delivery catheter to a region of interest;

fixing the inner core relative to the stabiliser component; and

30 deploying the self expanding stent by engaging the inner core with the proximal end of the stent.

70 A method as claimed in claim 69 wherein the stent is deployed by sliding the outer sheath and stent proximally to engage the inner core with the proximal end of the stent, the inner core engagement frictionally decoupling the stent and the sheath to deploy the stent.

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71 A method as claimed in claim 69 or 70 wherein the stent is frictionally coupled to the outer sheath in the delivery configuration.

72 A method as claimed in any of claims 69 to 70 comprising:

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introducing a procedural guidewire into the vasculature;

advancing the guidewire to a region of interest; and

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advancing the delivery system over the procedural guidewire.

73 A method as claimed in claim 72 wherein the method is of the rapid exchange type.

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74 A method as claimed in any of claims 69 to 73 comprising the steps of:

providing an embolic protection filter; and

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deploying the filter distal of the region of interest, in advance of introduction of the delivery system.

75 A method as claimed in claim 74 wherein the filter is mounted on the guidewire.

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76 A method as claimed in claim 74 wherein the filter is mountable to the guidewire.

77 A method as claimed in any of claims 69 to 76 wherein the region of interest is a region of stenosis in an arterial vessel having a tortuous passageway leading thereto.

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78 A method as claimed in claim 77 wherein the arterial vessel is a carotid artery.

79 A method as claimed in claim 77 wherein the arterial vessel is a superficial femoral artery.

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80 A method as claimed in claim 77 wherein the arterial vessel is a renal artery.

81 A method as claimed in any of claims 69 to 74 wherein the inner core is fixed relative to a component of the system.

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82 A method as claimed in claim 75 wherein the component is a guide catheter.

83 A method as claimed in claim 75 or 76 wherein the component is a Touhy Borst.

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84 A method as claimed in any of claims 69 to 77 wherein the system comprises a stabiliser fixed at a proximal end to the handle and the method comprises fixing the stabiliser to a component of the system.

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85 A method as claimed in claim 78 wherein the method comprises fixing the distal end of the stabiliser to a guide catheter.

86 A method as claimed in claim 78 or 79 wherein the method comprises fixing the distal end of the stabiliser to a Touhy Borst.

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87 A method for delivery and deployment of a self expanding stent comprising the steps of:

providing a delivery system providing:

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a catheter shaft having a proximal end and a distal end, the distal end of the shaft defining a reception space for receiving a self expanding stent, the stent having a reduced diameter delivery configuration;

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an inner core engagable with the proximal end of the stent;

an external mounting for the inner core; and

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an operator actuating element for the catheter shaft; and

moving the operating actuating element proximally of the external mounting to move the catheter shaft relative to the inner core to deploy the stent.

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88 A method as claimed in claim 87 wherein the operator handle is a pull handle and the catheter shaft is pulled proximally of the inner core to deploy the stent.

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